Memorandum

Date: September 20, 2019

To: Sterigenics, Willowbrook I, Construction Permit Application

File 19060030

From: Chris Romanne and Eric Jones

Subject: Evaluation of the Emission Control Technology for Ethylene

Oxide for Willowbrook I with the Upgrades Addressed in this

Application

In Construction Permit Application 19060030, Sterigenics has proposed significant upgrades to the emission control measures for ethylene oxide at the Willowbrook I facility. Pursuant to Section 9.16(g) of the newly-adopted amendments to the Illinois Environmental Protection Act, "Control of Ethylene Oxide Sterilization Sources," the Illinois EPA must determine whether the upgrades to the emission control system for Willowbrook I addressed in Permit Application 19060030 would result in this facility's emission control system using technology that produces the greatest reduction in emissions of ethylene oxide currently available.

As discussed in this memorandum, this standard will be met. The physical upgrades to the emission control system would result in the Willowbrook I facility using technology for capture and control of emissions of ethylene oxide that would provide the greatest reduction in emissions that is currently available. In addition, the facility would be required to operate and maintain this technology to comply with emission standards, as set forth in new Section 9.16(b) of the Act, that represent the greatest reduction in emissions of ethylene oxide that is currently available. In particular, Section 9.16(b) of the Act now will require that facilities in Illinois such as Sterigenics, which would use ethylene oxide for sterilization, to have permanent total enclosure and emissions of ethylene oxide then controlled by at least 99.9 percent or to no more than 0.2 ppm.

Background

The sterilization of medical devices and equipment results in the release of ethylene oxide at several steps in the overall process. The initial source of these releases is the sterilization chambers in which the material to be sterilized is placed and gaseous ethylene oxide is introduced to carry out the actual sterilization of the material. Most of the release of ethylene oxide occurs while the chambers are sealed and are being evacuated or purged using vacuum pumps in a series of vacuum cycles. This process removes most of the ethylene oxide from a chamber before the door is unsealed and the pallets of sterilized material are taken out. USEPA generally

considers these gas streams to constitute about 95 percent of the release of ethylene oxide at a sterilization facility. These streams have been a major focus of emission control and regulation and have been controlled at Willowbrook I with a wet acid scrubber. Wet acid scrubbers control emissions of ethylene oxide by conversion of the ethylene oxide to ethylene glycol in a reaction that is facilitated catalytically by the acid in the water-scrubbing solution. As will be discussed below, Sterigenics is now proposing to further control the streams from evacuation of the sterilization chambers with three additional control devices, in series, following the existing scrubber.

Release of ethylene oxide from the sterilization chambers also occurs through backvents on the sterilization chambers. The backvent or chamber exhaust vent on a sterilization chamber is used to complete the purging of a chamber after the chamber door is opened while sterilized product is still in the chamber. USEPA generally considers that the backvents constitute about 1 percent of the release of ethylene oxide at a sterilization facility. Control of these gas streams is not required under the current NESHAP rules. However, at Willowbrook I, backvent streams have been controlled by an Advanced Air Technology (AAT) wet acid scrubber followed by an AAT absorption control device. The absorption device uses a proprietary, dry reactant media that operates on the principle of chemical absorption to convert ethylene oxide into polyethylene. Sterigenics is now proposing to use an additional control device in series, a second AAT absorption device, to control the streams from the backvents on the sterilization chambers at Willowbrook I.

The second source of release of ethylene oxide from the sterilization process are the pallets of material that have undergone sterilization. Unreacted ethylene oxide is contained in this material. The pallets from the sterilization chambers must undergo aeration at a facility before being shipped. The aeration step occurs in heated rooms with forced ventilation to facilitate the loss of residual ethylene oxide from the sterilized product, with degassing and further reaction to prepare the sterilized product for shipment. USEPA generally considers that aeration contributes about 4 percent of the release of ethylene oxide at a sterilization facility. At Willowbrook I, the gas streams from aeration rooms have been controlled with the same control train as the backvents, i.e., an AAT wet acid scrubber followed by an AAT absorption control device. As already mentioned, a second AAT absorption device is now proposed to be added to this control train.

The other source of release of ethylene oxide from a sterilization process involves the other activities and areas other than the sterilization chambers and aeration rooms. At an ethylene oxide sterilization facility, ethylene oxide is released in the work aisle. This is the area between the front side of the sterilization chambers

and the doorways or passageways to the aeration rooms in which pallets of sterilized material are transported between a chamber and an aeration room. Ethylene oxide is released in this area, both directly from the chambers and from the sterilized product as it is transferred to aeration. (While the chambers do have capture hoods above the doors, these hoods were operated for worker protection and safety and the captured air streams were vented to the atmosphere without being controlled.) After aeration, sterilized product is kept in a storage area and/or a staging area pending shipment. These areas also have the potential for release of ethylene oxide as it is connected with the work aisle. In addition, residual ethylene oxide in the sterilized material may be released during storage. The storage area is served by general building ventilation. The release of ethylene oxide from these incidental operations are at most a fraction of 1 percent. In this regard, USEPA has not disseminated a factor to account for the release of ethylene oxide from these operations. Sterigenics is now proposing to control these incidental operations at Willowbrook I by making changes to achieve permanent total enclosure and installing an AAT absorption control device to specifically control gas streams that currently go directly to the atmosphere.

General Discussion of the Upgraded Emissions Control Technology

In Construction Permit Application 19060030, Sterigenics has proposed major upgrades to the emission control measures for ethylene oxide at the Willowbrook I facility. For a facility like Willowbrook I, in which emissions may be released to the atmosphere through building ventilation, it is necessary to consider the effectiveness of both the capture and the control of emissions.

Capture of Emissions

With the proposed upgrades of the control system, all releases of ethylene oxide of the Willowbrook I facility would be addressed with permanent total enclosure, so as to capture 100 percent of the emissions of ethylene oxide. The capture of 100 percent of the emissions of the facility or "permanent total enclosure" with those emissions then being ducted to emission control equipment is one of the new requirements that apply to Willowbrook I pursuant to Section 9.16(b) of the Act. As permanent total enclosure would be provided, the upgraded emission control system would address all emissions of ethylene oxide from the facility. In addition to emissions associated with the sterilization chambers and aeration rooms, emissions from the work aisle, the storage area for sterilized product and other internal areas at the facility would be addressed. Achievement of permanent total enclosure for the facility would be confirmed by initial operational testing, followed by operational monitoring for the pressure differential between the enclosed area inside the building and the outside of the building.

Control of Emissions

In conjunction with complete capture, the ethylene oxide emissions of the facility would be controlled in a manner that would provide the greatest reduction in emissions. In this regard, the air pollution control equipment for ethylene oxide would be set up to provide very effective control of the captured ethylene oxide. Effective operation of the control devices would be confirmed by annual emissions testing accompanied by continuous emissions monitoring for the facility, which would now exhaust to the atmosphere through a single stack, and other operational monitoring and recordkeeping.

In particular, the emissions from the evacuation of the sterilization chambers, which is the operation at the facility contributing the most emissions of ethylene oxide, would have the most control devices, four control devices in series. The initial control devices would be two existing "acid scrubbers." These devices use water-acid solutions to destroy ethylene oxide by catalytically facilitating the transformation of the ethylene oxide in the gas stream to ethylene glycol. Acid scrubbing is effective in controlling emissions of ethylene oxide. These devices can handle variations in the concentration of ethylene oxide in the gas stream, as occurs during operation of a facility with a number of sterilization chambers that operate as batch processes. These scrubbers would be very effective in controlling the bulk of the ethylene oxide in the gas stream from evacuation of the sterilization chambers at the Willowbrook I facility.

The ethylene oxide remaining in the gas stream after scrubbing would then be controlled by two dry-bed absorption devices in series. devices would use a proprietary agent or media that has been developed for control of ethylene oxide, rather than activated carbon or a zeolite material. Copies of material from the manufacturer of these dry-bed devices for ethylene oxide are attached as Appendix A, along with copies of other material that was reviewed related to technology for control of emissions and control of emissions of ethylene oxide. The scrubbers preceding the first absorption device would enable absorption to take place effectively without being overwhelmed by the level of ethylene oxide in the gas stream from evacuation of the sterilization chambers prior to scrubbing. The media in the absorption devices would gradually be deactivated or consumed by the control of ethylene oxide. The media in the individual beds in each device would be replaced with fresh media as needed to maintain the effective further control of ethylene oxide. The absorption devices could continue to operate while the media is being replaced, with only one bed in a device taken out of service at a time for replacement of its In addition, as this media would not be regenerated and the spent media would be disposed of, the control effectiveness of the absorption devices would not be reduced by the periodic regeneration of sorbent material in individual beds. Also, the absorption devices

would be in series, with the new second absorption device acting as a polishing or final control device. This would act to increase the effectiveness of control of the gas stream from evacuation of the sterilization chambers, as the gas stream would undergo absorption twice. It would also provide a "redundant" absorption device ensuring effective control of ethylene oxide.

A similar approach would be used to control ethylene oxide in the gas streams from the aeration rooms and the backvents on the sterilization chambers. Ethylene oxide in these streams would be controlled using the second acid scrubber and the same absorption devices for these streams as used for the gas streams for evacuation of the sterilization chambers. The acid scrubber would control the bulk of the ethylene oxide in these gas streams. The scrubber would also address potential variation in the level of ethylene oxide in these streams, which is less than the variation in the gas stream from evacuation of the sterilization chambers. The ethylene oxide remaining in the gas stream after scrubbing would then be controlled by the two dry-bed absorption devices in series. The new absorption device would both increase the effectiveness with which the gas streams from the aeration rooms and the back vents would be controlled and serve to provide redundancy in control of these streams.

The emissions of the work aisle and product storage area, which would now be captured with permanent total enclosure, would be controlled by a new AAT absorption device. Given the characteristics of this gas stream, this device is appropriate for control of emissions. The low concentration of ethylene oxide in the stream would be such that the performance of this device stream would not benefit from initial control of the stream with a wet acid scrubber. Appropriately designed absorption devices are very effective in removing low concentrations of organic compounds from air streams.

Review of Emission Control Systems Used at Other Sources

A review of air pollution control permits and other related documents for other sources engaged in commercial ethylene oxide sterilization shows that with the improvements to the emission control system at the facility, these systems would use technology that would produce the greatest reduction in emissions. A summary of the information assembled for other sources is provided in attached Table 1.1 through 1.16. Copies of the material on which each of these tables are based are attached as Appendix B.

This review of other sources shows that emissions at other ethylene oxide sterilization sources are commonly controlled with devices of the type that are present at the Willowbrook I facility, i.e., acid scrubbers and a dry-bed absorption device. However, at a significant number of sources, afterburners or oxidation is used to control

emissions, either on its own or in combination with other types of control devices.

Oxidation, whether catalytic or thermal, should not be considered a more effective technology than the technology that is currently in place at the facility. While oxidation is an appropriate choice for control technology for many types of emission units, this would not be the case for Willowbrook I. Oxidation is most effective when the concentrations of the organic compounds that are controlled are high and consistent. Under these "ideal" conditions, 98 or 99 percent efficiency is commonly achievable. However, at low or variable concentrations, the efficiency of control is lower. To address this phenomenon, performance of oxidizers for emission units where the concentrations of uncontrolled emissions may at times be low, is often best addressed by setting two different limits, one for control efficiency and one for the concentration of the target compound in the exhaust stream. At high concentrations, the efficiency limit governs. At low concentrations, where combustion is less efficient, the concentration limit governs. These "stopper limits" are often set at 10 or 20 ppmv.² Even for ethylene oxide sources that use oxidation control, these stopper limits are typically set at 1 ppmv, well above the 0.2 ppmv concentration limit that is applicable for this facility.3 In summary, oxidation technology should not be considered to provide more effective control of emissions than the control devices currently at the facility.

The review of the information for emission control systems at other sources also identifies aspects of the future emission control system at the Willowbrook I facility that support a finding that the system would use using technology for capture and control of emissions of ethylene oxide that would provide the greatest reduction in emissions

 $^{^1}$ In the Air Pollution Control Technology Fact Sheet, EPA-452/F-03-022, prepared by USEPA, USEPA uses as an example an oxidizer that is required to meet either 98 percent or greater control or an exit concentration for the compound of 20 ppmv.

 $^{^2}$ This illustrates the fact that it is appropriate to consider the context in which representations for the performance of control devices are made. The presence of any accompanying supporting or background information or any qualifications or any limitations on the representations is also relevant. There may be a striking difference between the performance of control devices depending on the types of emissions units to which they are applied and the modes of operation of those units. ³ One of the facilities that was identified as using catalytic oxidation to control emissions is Boston Scientific Corporation in Coventry, Rhode Island. It is noteworthy that the permit that was obtained for the facility, which was issued in 2010, has requirements for the sterilization chambers and aeration rooms that apply downstream of their respective acid scrubbers before the gas stream enters the shared oxidizer. For the sterilization chambers, 99.5 percent reduction is required. For the aeration rooms, emissions must be reduced to a maximum concentration of 1 ppmv or 99.9 percent reduction, whichever is less stringent. A separate requirement for control of emissions is set relative to the oxidizer, i.e., a reduction of 99.0 percent unless outlet emissions are below the greater of the lower limit of detection for the stack test or 0.8 ppmv. In practice, this provision could require little, if any, further control of emissions by the oxidizer beyond the control provided by the scrubbers.

that is currently available. First, permanent total enclosure would be required. At certain other sources, negative pressure inside the building is required but the criteria of Method 204 are not currently imposed.^{4, 5}

Second, the control train for the sterilization chambers and aeration rooms would include a primary dry-bed absorption device followed by a second dry-bed absorption device. This practice does not appear to be used at other sources. This configuration, with active and reserve absorption capacity, is best practice for emission units that are controlled by absorption devices that are not regenerated in-situ.

Third, at the facility, the concentration of ethylene oxide entering the initial, active dry-bed device would be lowered by the preceding scrubber(s), which will facilitate consistent, low concentrations of ethylene oxide entering the device and very effective further removal of ethylene oxide. For the evacuation of the sterilization chambers, which releases most of the ethylene oxide, there would be two scrubbers in series.

Lastly, use of a separate dry-bed device for "other releases" is a control measure that would only be used by Sterigenics in Willowbrook and Atlanta. In summary, the review of emission control systems at other sources shows that the control system at the Willowbrook I facility would use control devices that use technology that provide the greatest reduction in emissions of ethylene oxide currently available, including both the types of devices that would be used and how they would be arranged in the emission control system.

Discussion of the Required Level of Control

A review of the current emissions standards of various air pollution control authorities, including the USEPA, confirms that emission standards that are more stringent than those in Section 9.16(b) of the Act have not been adopted for ethylene oxide sterilization sources.

A summary of emission control requirements of other air pollution control authorities for large commercial sterilization facilities that would be applicable to Willowbrook I if it were located in those

In particular, the Consent Order issued on August 7, 2019, for Sterigenic's facility in Atlanta does not provide for permanent total enclosure. Although one of the proposed improvements that would be made to this facility pursuant to a recent construction permit would be to install a dry-bed absorption device for control of ethylene oxide in the indoor air, Sterigenic's application does not address the criteria for permanent total enclosure.

⁵ At some facilities, capture of emissions is only addressed indirectly. For example,

The Permittee shall take all reasonable precautions with any operation, process, handling transportation or storage facilities to prevent fugitive emissions of air contaminants.

State of Georgia, Department of Natural Resource, Environmental Protection Division, Permit No. 3841-211-S-04-0, issued January 9, 2019.

jurisdictions is attached, Table 2. Also included are the control requirements of the USEPA's National Emission Standard for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Sterilization Facilities, 40 CFR 63 Subpart O, that currently apply on a national basis to facilities like the Willowbrook I facility. Copies of the material on which Table 2 is based are attached as Appendix C.

As summarized in Table 2, various air pollution control authorities have adopted emission standards that are more stringent than those in 40 CFR 63 Subpart O. However, with respect to capture of emissions, none explicitly require 100 percent capture for all emissions. Indeed, only the California Air Resources Board (CARB) and Eastern County Air Quality Maintenance District (AQMD), explicitly address capture efficiency and only do so for aerations rooms, with a requirement for 100 percent capture. Only North Carolina addresses the work aisle or "product transfer," with a requirement that it be kept under negative pressure accompanied by control of the emissions. 6

With respect to control of emissions, several jurisdictions require 99.9 percent reduction for the evacuation of the sterilization chambers. North Carolina requires 99.8 percent reduction or emissions of no more than 0.2 ppm. For aeration rooms, two jurisdictions, Eastern Kern County AQMD and San Joaquin County AQMD require 99.9 percent reduction or emissions of no more than 0.2 ppm. For the backvents, several jurisdictions require 99 percent reduction. However, with respect to the work aisle, control is only required by North Carolina to accompany the requirement for negative pressure, 99 percent reduction or 1 ppm. In summary, based on this information, Illinois now has the most stringent control requirements anywhere in the United States for emissions of ethylene oxide from commercial sterilization facilities.

⁶ For commercial sterilization facilities using 2000 pounds of ethylene oxide or more per year, the California Air Resources Board does not have a requirement for permanent total enclosure at subject facilities. However, it does have a requirement that applies to piping and ductwork at these facilities. The exhaust systems and ethylene oxide supply through which ethylene oxide is conveyed to and from the sterilizer, aerator and control devices are required to be leak-free. A "leak-free" state is defined to exists when the concentration of ethylene oxide measured 1 centimeter away from any portion of the surface is less than 10 ppm.

Table 1.1: Arkansas			
Baxter Healthcare Corporation,	ration, Mountain Home¹		8
Arkansas Department of	Arkansas Department of Environmental Quality, Office of Air Quality	ality	
ADEQ Minor Source Air Pa	ADEQ Minor Source Air Permit No. 0544-AR-16, May 8, 2019		8
Sterilization Chambers	Sterilization Chambers Aeration Rooms	Rooms (Indoor Air)	loor Air)
(Evacuation)	(Backvents)		
Acid Scrubber	Acid Scrubber (same as Catalytic Oxidizers	dizers -	
	sterilization		-
	chambers) 1		
Notes:	2.		
1. This source also man	This source also manufactures plastic medical devices.		
2. The permit also prov	2. The permit also provides that in the case of emergency or upset conditions that could impact	pset conditions that cou	ild impact
personnel safety, backvents ma	ents may be exhausted to the atmosphere.	-	
Comments:			
None			
	1		

Table 1.2: Colorado			
Terumo BCT Sterilization Service Inc, Lakewood	Service Inc, Lakewood		
Colorado Department of P	ublic Health and Environ	Colorado Department of Public Health and Environment, Air Pollution Control Division	ol Division
Notice of a Proposed Pro	Notice of a Proposed Project or Activity Warranting Public Comment ¹	ing Public Comment ¹	
Draft Construction Permi	t, Permit No. 96JE871:	Draft Construction Permit, Permit No. 96JE871: Issuance 6, August 22, 2019	61
Sterilization Chambers	Sterilization Chambers	Jorotton Booms	Other (Indoor Air)
(Evacuation)	(Backvents)	Actacton Norms	
Catalytic thermal	Catalytic thermal	Catalytic thermal	1
oxidizer	oxidizer (same)	oxidizer (same)	
Notes:			
1. Emissions of ethylene oxide	oxide from the source w	from the source would be limited by the draft permit to 1.8	ift permit to 1.8
tons/year, a decrease from	from 5.4 tons/year.		
Comments:			
None			

Table 1.3: Georgia - 1			
BD (Becton, Dickinson and Company), Madison	nd Company), Madison		
Georgia Department of Natural	atural Resources, Environ	Resources, Environmental Protection Division	uc
Air Quality Permit No. 3841-21	3841-211-0021-S-04-0, January 9, 2019	uary 9, 2019	
Sterilization Chambers	Sterilization Chambers	Acretion Booms	Other (Indoor Air)
(Evacuation)	(Backvents)	Detacton Norms	
Regenerative Thermal	Regenerative Thermal	Regenerative Thermal	
Oxidizer	Oxidizer	Oxidizer	
	(same)	(same)	
Notes:			
1. For fugitive emissic	. For fugitive emissions, per Condition 3.1, "The Permittee shall take all reasonable	The Permittee shall take	all reasonable
precautions with any operation,		process, handling, transportation, or storage facilities to	orage facilities to
prevent fugitive emissions of	ons of air contaminants."		
Comments:			
None			

Table 1.4: Georgia - 2			
KPR U.S., LLC (d/b/a Kendall Patient Recovery U.S., LLC), Augusta1	1 Patient Recovery U.S.	., LLC), Augusta ¹	
Georgia Department of Natural	_	Resources, Environmental Protection Division	u
Air Quality Permit No. 3842-245-0109-S-05-0, September 27, 2017	-245-0109-S-05-0, Sept	tember 27, 2017	
Sterilization Chambers Ste	Sterilization Chambers	Sovertion Dooms	Other (Indoor Air)
(Evacuation)	(Backvents)	Detacton mode	
Catalytic Oxidizer ² -3		-3	14
Notes:			
1. This source also manufactures alcohol prep pads	actures alcohol prep p	ads	
2. The two sterilization c	chambers also have rec	The two sterilization chambers also have recovery systems for ethylene oxide.	ene oxide.
3. The permit does not address backvents on the sterilization chambers or separate	ress backvents on the s	sterilization chambers o	r separate aeration
rooms.			
4. For fugitive emissions, per		Condition 3.1, "The Permittee shall take all reasonable	all reasonable
precautions with any operation,		process, handling, transportation, or storage facilities	rage facilities to
prevent fugitive emissions of	of air contaminants."		
Comments:			
None.			

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			uo			Other (Indoor Air)		Dry Bed Device (to be	installed) 3					
	Atlanta		mental Protection Division	July 30, 2019¹		Aeration Rooms		Same control system as	backvents (existing)			*		
	tlanta Facility, Smyrna/Atlanta	1-8-05-0	Georgia Department of Natural Resources, Environmental Protection Division	SIP Application for Emission Reduction Project, July 30, 20191	80, August 7, 2019	Sterilization Chambers	(Backvents)	Acid Scrubber followed	by Dry Bed Device	(existing)				
M-1-1-4 A. Coonein - 2	Sterigenics U.S., LLC, Atlanta	Permit No. 7389-067-0093-S-05-	Georgia Department of Na	SIP Application for Emis	Consent Order EPD-AQC-6980, August 7, 2019	Sterilization Chambers	(Evacuation)	Acid Scrubber	(existing)2 followed by by Dry Bed Device	a Second Acid Scrubber	and Dry Bed Device	(connection to the	existing scrubber to	be installed)

1. Sterigenics has also submitted an application for improvements to the emission control measures at its facility in Atlanta. Notes:

2. An existing permit also addresses use of the existing control system for the backvents and aeration room as an alternative to this existing scrubber.

enclosure, the consent order describes all indoor emissions being routed through the new dry bed 3. While the application for improvements to the facility does not address permanent total device.

the existing scrubber that normally controls the evacuation of the sterilization chambers will Similar to the improvements that are to be made to the Willowbrook facility, the exhaust from be connected to the existing control system for the backvents and aeration rooms. second dry bed device is not planned for the existing control system. Permanent total enclosure is not proposed or explicitly required. Comments:

However, a

Table 1.5: Indiana			
Cook Incorporated, Elletsville	sville	334	
Federally Enforceable Sta	ate Operating Permit (FE:	Federally Enforceable State Operating Permit (FESOP) No. F 105-40744-0030	
Indiana Department of Environmental Management	/ironmental Management		
Administrative Amendment to FESOP, February 25, 2019	to FESOP, February 25,	2019	
Draft FESOP Renewal, July 18, 2019	7 18, 2019		
Sterilization Chambers	Sterilization Chambers	Aeration Rooms	Other (Indoor Air)
(Evacuation)	(Backvents)		
Wet acid scrubbers ²	Dry bed absorbers ²	Dry bed absorbers ³	
Notes:			
1. The sterilization chambers		exhaust to two wet acid scrubbers, seven to one scrubber and two	one scrubber and two
to the other.		***	
2. The backvents of the	sterilization chambers	The backvents of the sterilization chambers also exhaust to two separate dry bed absorbers,	te dry bed absorbers,
each with three beds.			
3. Of the 14 aeration ro	soms, six can exhaust to	3. Of the 14 aeration rooms, six can exhaust to a wet acid scrubber followed by a dry bed	wed by a dry bed
absorber with three beds.	The	remaining aeration exhaust to a separate dry bed absorber with	y bed absorber with
three beds.			
Comments:			
None			

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The Jackson Laboratory, Bar Harbor Permit No. A-93-71-X-R (SM)

State of Maine, Department of Environmental Protection

Air Emissions License Renewal, November 24, 2014

Notes:

The permit limits usage of ethylene oxide to no more than 1.0 ton/year and requires minimal emissions. This facility is an independent, nonprofit, biomedical research institution.

Comments:

None

Table 1.7: Michigan - 1			
Centurion Medical Products, Howe	ts, Howell		
Michigan Department of Environmental Quality, Air Quality Division	nvironmental Quality, Ai.	r Quality Division	
Permit to Install Permit	Permit to Install Permit No. 24-94B, August 17, 2017	2017	
Sterilization Chambers	Sterilization Chambers	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Other (Indoor Air)
(Evacuation)	(Backvents)	Peracton Noom	_1
Thermal oxidizer	Dry bed absorber	Dry bed absorber	1
		(same)	

Notes:

1. The permit indicates that the product transfer corridor associated with the aeration room is vented to the aeration room.

Comments: None

Table 1.8: Michigan - 2			
Viant Medical, Inc, Grand Rapids	d Rapids		
Michigan Department of Environmental Quality, Air Quality Division	Environmental Quality, A	ir Quality Division	
Site Visit Summary, August 6,	ust 6, 2018		
Sterilization Chambers1	Sterilization Chambers	Deration Rooms	Other (Indoor Air)
(Evacuation)	(Backvents)		
Acid scrubbers1	Acid scrubber	Acid scrubber	-2
Notes: 1. The site visit summary references Permit to Install 605-89B. 2. The sterilization chambers exhaust to two acid scrubbers in controls the backvents and aeration rooms.	ry references Permit to ambers exhaust to two ac nd aeration rooms.	rences Permit to Install 605-89B. exhaust to two acid scrubbers in series. The second scrubber also tion rooms.	The second scrubber also
Comments: In March 2019, Viant announced		publicly that this plant would close later in 2019.	r in 2019.

Midwest Sterilization Corporation, Jackson	oration, Jackson		
Missouri Department of Natural		Resources, Missouri Air Conservation Commission	ssion
Permit to Construct No. 062019-001, June 5, 2019 (Project Number 031-0068)	52019-001, June 5, 2019	(Project Number 031-0068	3}
Sterilization Chambers S	Sterilization Chambers	April and Access	Other (Indoor Air)
(Evacuation)	(Backvents)	veración nooms	
Wet scrubber We	Wet scrubber ¹	Dry bed absorber	
Notes:			
1. This construction perm	nit addresses construct.	This construction permit addresses construction of the wet scrubber for the backvents.	or the backvents. The
backvents were previously controlled along with the aeration rooms.	controlled along with	the aeration rooms.	
Comments:			
None			

Table 1.10: New York			(%
Sterigenics U.S., LLC, Queensbu	Queensbury		
Permit No. 5-5344-00029/00011	/00011		
New York State Departmer	New York State Department of Environmental Conservation	rvation	
Permit Modification 4, February	February 2013		
Sterilization Chambers ¹	Sterilization Chambers	Acretion Doome2	Other (Indoor Air)
(Evacuation)	(Backvents)	ACTACTOIL MODINS	
Acid scrubber or	Catalytic oxidizer	Catalytic oxidizer	ı
catalytic oxidizer			
Notes:			
	100		
Comments:			
None			

Table 1.11: North Carolina - 1	ina - 1		=
Andersen Products, Inc., Haw River	, Haw River ¹		
Permit No. 05501R10			
North Carolina Departmer	North Carolina Department of Environment and Natural Resources, Division of Air Quality	ural Resources, Division	of Air Quality
Construction and Operati	Construction and Operation Permit, July 9, 2014		
Sterilization ²	Sterilization Chambers	2 C C C C C C C C C C C C C C C C C C C	Other (Indoor Air)
	(Backvents)	Aeracion rooms	
Abators ³	_ d =	4-	-5
3			II.

Notes:

- Usage of ethylene 1. This facility manufactures glass ampoules containing ethylene oxide. oxide is less than 2,000 pounds/year.
- 2. The facility has sterilization and aeration chambers, a sterijet machine and "ethylene oxide 3. The abators use either a resin or a combination of a resin and activated carbon as the cabinets."
- 4. The permit does not address separate backvents on the sterilization equipment or aeration absorption media: rooms.
 - 5. A trash can at the facility is also controlled with an abator

Comments:

Comments None.

Table 1.12: North Carolina - 2	na - 2		
Arrow International, Inc Asheboro, Asheboro	Asheboro, Asheboro		_
Permit No. 06756R08			
North Carolina Environmental Management Commission	intal Management Commissi	on	
North Carolina Environmental Quality - Air Quality	intal Quality - Air Quali	ty	
Construction and Operation Permit, April 21, 2016	on Permit, April 21, 201	9	
Sterilization Chambers	Sterilization Chambers		Other (Indoor Air)
(Evacuation)	(Backvents)	ACTACION NOUNS	
Catalytic Oxidizer	_1	Catalytic Oxidizer	1
		(same)	
Notes:			*2)
1 The normit does not	The nermit does not separately address backyents on the sterilization chambers.	ents on the sterilizatio	n chambers.

1. The permit does not separately address backvents on the sterilization chambers.
2. The permit addresses two aeration cells and one aeration room.
Comments:

None

Table 1.13: North Carolina - 3	හ ස		
Sterigenics U.S., LLC, Charlotte	arlotte		
Permit No. 14-017-959			
Mecklenburg County Land Use and		Environmental Services Agency - Air Quality	-ty
Reissuance of Permit No. 14-017-959, April 8, 2014	14-017-959, April 8, 20	14	
Sterilization Chambers S	Sterilization Chambers	30x14+0x00	Other (Indoor Air)
(Evacuation)	(Backvents)	ACTACTON NOOMS	
Acid scrubber	Catalytic Oxidizer	Catalytic Oxidizer	_1
	48	(same)¹	
Notes:			
1. The product aeration and product transfer area shall also be maintained under a negative	and product transfer are	ea shall also be maintain	ned under a negative
pressure.			
		**	
Comments:			52
None			

Table 1.14: Pennsylvania			
B Braun Med Inc, Allentown	um		
Pennsylvania Department	of Environmental Protect	Pennsylvania Department of Environmental Protection - Air Quality Program	u
Title V/State Operating Permit		Permit No. 39-00055, August 31, 2016	
Sterilization Chambers	Sterilization Chambers	Acration Rooms	Other (Indoor Air)
(Evacuation)	(Backvents)		**
Acid scrubber	· -	Catalytic oxidizer4	
Notes:			
1. The permit does not	separately address the b	The permit does not separately address the backvents on the aeration chambers.	chambers.
	* = .		
Comments:			
None			

Table 1.16: Rhode Island			
Boston Scientific Corporation,	tion, Coventry		
Rhode Island Department of Environmental Management, Office of Air Resources	f Environmental Managem	ent, Office of Air Resour	rces
Approval No. 2114, September 30, 2010	oer 30, 2010		
Sterilization Chambers S	Sterilization Chambers	Aeration Rooms	Other (Indoor Air)
(Evacuation)	(Backvents)		
Acid scrubber followed C	Catalytic oxidizer	Acid scrubber followed	Sterilizer hoods and
by catalytic oxidizer ² ((same)	by catalytic oxidizer	ethylene oxide storage
		(same)	room: Catalytic
			oxidizer (same)
Notes:	8-		
Comments:			
None			

	Table 2: Cont Ethylene	: Control Requirements for Operations at hylene Oxide Sterilization Sources	Operations at n Sources	
		obe	Operation	
Jurisdiction	Sterilizer Chamber Evacuation	Aeration Rooms	Sterilizer Chamber Back Vents	Other Operations
State of Illinois	100% capture of em 0.2 ppm for each e	emissions (permanent texhaust point	cotal enclosure) wi	emissions (permanent total enclosure) with 99.9% reduction or exhaust point
USEPA (National)	1 =	99% reduction or 1 ppm	Not addressed	Not addressed
State of California (California Air Resources Board)	99.9% reduction	100% capture and 99% control or 1	99% reduction	Components & ductwork for sterilizers and aeration: Leak free
State of North Carolina	99.8% reduction or 0.2 ppm	99% reduction or 1 ppm	99% reduction or 1 ppm	Product transfer: Under negative pressure and either 99% reduction or 1 ppm
San Joaquin Valley	99.9% reduction or 0.2 ppm	99.9% reduction or 0.2 ppm	Not addressed	Not addressed
Eastern Kern County AQMD, California	99.9% reduction or 0.2 ppm	99.9% reduction or 0.2 ppm	Not addressed	Not addressed